

Attorney Docket No.: DEX-0117
Inventors: Salceda et al.
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This listing of the claims will replace all prior versions and listings of claims in the application:

Listing of the claims:

Claims 1-2 (canceled)

Claim 3 (currently amended): A method for diagnosing the presence of breast cancer in a patient comprising:

(a) determining levels of Breast Cancer Specific Gene (BCSG) polynucleotide in cells, tissues or bodily fluids in a patient; and

(b) comparing the determined levels of BCSG polynucleotide with levels of BCSG polynucleotide in cells, tissues or bodily fluids from a normal human control, wherein an increase in determined levels of BCSG polynucleotide in said patient versus normal human control is associated with the presence of breast cancer and wherein the BCSG polynucleotide comprises SEQ ID NO:~~1, 2, 4, 5, or~~ 1 or 2 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO:~~1, 2, 4, 5, or~~ 1 or 2.

Claim 4 (currently amended): A method of diagnosing metastases of breast cancer in a patient comprising:

(a) identifying a patient having breast cancer that is not known to have metastasized;

(b) determining Breast Cancer Specific Gene (BCSG) polynucleotide levels in cells, tissues, or bodily fluid from said patient; and

(c) comparing the determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissue, or

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bodily fluid of a normal human control, wherein an increase in determined BCSG polynucleotide levels in the patient versus the normal human control is associated with breast cancer which has metastasized and wherein the BCSG polynucleotide comprises SEQ ID NO: ~~1, 2, 4, 5, or 18~~ 1 or 2 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: ~~1, 2, 4, 5, or 18~~ 1 or 2.

Claim 5 (currently amended): A method of staging breast cancer in a patient having breast cancer comprising:

- (a) identifying a patient having breast cancer;
- (b) determining Breast Cancer Specific Gene (BCSG) polynucleotide levels in a sample of cells, tissue, or bodily fluid from said patient; and
- (c) comparing determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissues, or bodily fluid of a normal human control, wherein an increase in determined BCSG polynucleotide levels in said patient versus the normal human control is associated with breast cancer which is progressing and a decrease in the determined BCSG polynucleotide levels is associated with breast cancer which is regressing or in remission and wherein the BCSG polynucleotide comprises SEQ ID NO: ~~1, 2, 4, 5, or 18~~ 1 or 2 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: ~~1, 2, 4, 5, or 18~~ 1 or 2.

Claim 6 (currently amended): A method of monitoring breast cancer in a patient for the onset of metastasis comprising:

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(a) identifying a patient having breast cancer that is not known to have metastasized;

(b) periodically determining levels of Breast Cancer Specific Gene (BCSG) polynucleotide in samples of cells, tissues, or bodily fluid from said patient; and

(c) comparing the periodically determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissues, or bodily fluid of a normal human control, wherein an increase in any one of the periodically determined BCSG polynucleotide levels in the patient versus the normal human control is associated with breast cancer which has metastasized and wherein the BCSG polynucleotide comprises SEQ ID NO: ~~1, 2, 4, 5, or 18~~ 1 or 2 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: ~~1, 2, 4, 5, or 18~~ 1 or 2.

Claim 7 (currently amended): A method of monitoring a change in stage of breast cancer in a patient comprising:

(a) identifying a patient having breast cancer;

(b) periodically determining levels of Breast Cancer Specific Genes (BCSG) polynucleotide in cells, tissues, or bodily fluid from said patient; and

(c) comparing the periodically determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissues, or bodily fluid of a normal human control, wherein an increase in any one of the periodically determined BCSG polynucleotide levels in the patient versus the normal human control is associated with breast cancer which is progressing in stage and a decrease is associated with breast cancer which is regressing in stage or in

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remission and wherein the BCSG polynucleotide comprises SEQ ID NO: ~~1, 2, 4, 5, or 18~~ 1 or 2 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: ~~1, 2, 4, 5, or 18~~ 1 or 2.

Claims 8-17 (canceled)

Claim 18 (currently amended): The method of claim 3 wherein the BCSG polynucleotide comprises SEQ ID NO: ~~1, 2 or 18~~ or 2.

Claim 19 (previously added): The method of claim 18 wherein the BCSG polynucleotide comprises SEQ ID NO: 1.

Claim 20 (previously added): The method of claim 18 wherein the BCSG polynucleotide comprises SEQ ID NO: 2.

Claim 21 (canceled)

Claim 22 (currently amended): The method of claim 4 wherein the BCSG polynucleotide comprises SEQ ID NO: ~~1, 2 or 18~~ or 2.

Claim 23 (previously added): The method of claim 22 wherein the BCSG polynucleotide comprises SEQ ID NO: 1.

Claim 24 (previously added): The method of claim 22 wherein the BCSG polynucleotide comprises SEQ ID NO: 2.

Claim 25 (canceled)

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Claim 26 (currently amended): The method of claim 5 wherein the BCSG polynucleotide comprises SEQ ID NO: 1,~~2~~~~or~~ 18 or 2.

Claim 27 (previously added): The method of claim 26 wherein the BCSG polynucleotide comprises SEQ ID NO:1.

Claim 28 (previously added): The method of claim 26 wherein the BCSG polynucleotide comprises SEQ ID NO:2.

Claim 29 (canceled)

Claim 30 (currently amended): The method of claim 6 wherein the BCSG polynucleotide comprises SEQ ID NO: 1,~~2~~~~or~~ 18 or 2.

Claim 31 (previously added): The method of claim 30 wherein the BCSG polynucleotide comprises SEQ ID NO:1.

Claim 32 (previously added): The method of claim 30 wherein the BCSG polynucleotide comprises SEQ ID NO:2.

Claim 33 (canceled)

Claim 34 (currently amended): The method of claim 7 wherein the BCSG polynucleotide comprises SEQ ID NO: 1,~~2~~~~or~~ 18 or 2.

Claim 35 (previously added): The method of claim 34 wherein the BCSG polynucleotide comprises SEQ ID NO:1.

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Claim 36 (previously added): The method of claim 34 wherein the BCSG polynucleotide comprises SEQ ID NO:2.

Claim 37 (canceled)

Claim 38 (new): A method for diagnosing the presence of breast cancer in a patient comprising:

(a) determining levels of Breast Cancer Specific Gene (BCSG) polynucleotide in cells, tissues or bodily fluids in a patient; and

(b) comparing the determined levels of BCSG polynucleotide with levels of BCSG polynucleotide in cells, tissues or bodily fluids from a normal human control, wherein an increase in determined levels of BCSG polynucleotide in said patient versus normal human control is associated with the presence of breast cancer and wherein the BCSG polynucleotide comprises SEQ ID NO: 18 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 18.

Claim 39 (new): A method of diagnosing metastases of breast cancer in a patient comprising:

(a) identifying a patient having breast cancer that is not known to have metastasized;

(b) determining Breast Cancer Specific Gene (BCSG) polynucleotide levels in cells, tissues, or bodily fluid from said patient; and

(c) comparing the determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissue, or bodily fluid of a normal human control, wherein an increase in determined BCSG polynucleotide levels in the patient

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versus the normal human control is associated with breast cancer which has metastasized and wherein the BCSG polynucleotide comprises SEQ ID NO: 18 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 18.

Claim 40 (new): A method of staging breast cancer in a patient having breast cancer comprising:

- (a) identifying a patient having breast cancer;
- (b) determining Breast Cancer Specific Gene (BCSG) polynucleotide levels in a sample of cells, tissue, or bodily fluid from said patient; and
- (c) comparing determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissues, or bodily fluid of a normal human control, wherein an increase in determined BCSG polynucleotide levels in said patient versus the normal human control is associated with breast cancer which is progressing and a decrease in the determined BCSG polynucleotide levels is associated with breast cancer which is regressing or in remission and wherein the BCSG polynucleotide comprises SEQ ID NO: 18 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO:18.

Claim 41 (new): A method of monitoring breast cancer in a patient for the onset of metastasis comprising:

- (a) identifying a patient having breast cancer that is not known to have metastasized;
- (b) periodically determining levels of Breast Cancer Specific Gene (BCSG) polynucleotide in samples of cells, tissues, or bodily fluid from said patient; and

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(c) comparing the periodically determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissues, or bodily fluid of a normal human control, wherein an increase in any one of the periodically determined BCSG polynucleotide levels in the patient versus the normal human control is associated with breast cancer which has metastasized and wherein the BCSG polynucleotide comprises SEQ ID NO:18 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO:18.

Claim 42 (new): A method of monitoring a change in stage of breast cancer in a patient comprising:

- (a) identifying a patient having breast cancer;
- (b) periodically determining levels of Breast Cancer Specific Genes (BCSG) polynucleotide in cells, tissues, or bodily fluid from said patient; and
- (c) comparing the periodically determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissues, or bodily fluid of a normal human control, wherein an increase in any one of the periodically determined BCSG polynucleotide levels in the patient versus the normal human control is associated with breast cancer which is progressing in stage and a decrease is associated with breast cancer which is regressing in stage or in remission and wherein the BCSG polynucleotide comprises SEQ ID NO:18 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO:18.

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Claim 43 (new): The method of claim 3 wherein levels of BCSG polynucleotide are determined in cells.

Claim 44 (new): The method of claim 3 wherein levels of BCSG polynucleotide are determined in tissues.

Claim 45 (new): The method of claim 3 wherein levels of BCSG polynucleotide are determined in bodily fluids.

Claim 46 (new): The method of claim 45 wherein the bodily fluid is whole blood, plasma, serum, a derivative of blood, urine, saliva or other bodily secretion.

Claim 47 (new): The method of claim 4 wherein levels of BCSG polynucleotide are determined in cells.

Claim 48 (new): The method of claim 4 wherein levels of BCSG polynucleotide are determined in tissues.

Claim 49 (new): The method of claim 4 wherein levels of BCSG polynucleotide are determined in bodily fluids.

Claim 50 (new): The method of claim 49 wherein the bodily fluid is whole blood, plasma, serum, a derivative of blood, urine, saliva or other bodily secretion.

Claim 51 (new): The method of claim 5 wherein levels of BCSG polynucleotide are determined in cells.

Claim 52 (new): The method of claim 5 wherein levels of BCSG polynucleotide are determined in tissues.

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Claim 53 (new): The method of claim 5 wherein levels of BCSG polynucleotide are determined in bodily fluids.

Claim 54 (new): The method of claim 53 wherein the bodily fluid is whole blood, plasma, serum, a derivative of blood, urine, saliva or other bodily secretion.

Claim 55 (new): The method of claim 6 wherein levels of BCSG polynucleotide are determined in cells.

Claim 56 (new): The method of claim 6 wherein levels of BCSG polynucleotide are determined in tissues.

Claim 57 (new): The method of claim 6 wherein levels of BCSG polynucleotide are determined in bodily fluids.

Claim 58 (new): The method of claim 57 wherein the bodily fluid is whole blood, plasma, serum, a derivative of blood, urine, saliva or other bodily secretion.

Claim 59 (new): The method of claim 7 wherein levels of BCSG polynucleotide are determined in cells.

Claim 60 (new): The method of claim 7 wherein levels of BCSG polynucleotide are determined in tissues.

Claim 61 (new): The method of claim 7 wherein levels of BCSG polynucleotide are determined in bodily fluids.

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Claim 62 (new): The method of claim 61 wherein the bodily fluid is whole blood, plasma, serum, a derivative of blood, urine, saliva or other bodily secretion.

Claim 63 (new): The method of claim 38 wherein levels of BCSG polynucleotide are determined in cells.

Claim 64 (new): The method of claim 38 wherein levels of BCSG polynucleotide are determined in tissues.

Claim 65 (new): The method of claim 38 wherein levels of BCSG polynucleotide are determined in bodily fluids.

Claim 66 (new): The method of claim 65 wherein the bodily fluid is whole blood, plasma, serum, a derivative of blood, urine, saliva or other bodily secretion.

Claim 67 (new): The method of claim 39 wherein levels of BCSG polynucleotide are determined in cells.

Claim 68 (new): The method of claim 39 wherein levels of BCSG polynucleotide are determined in tissues.

Claim 69 (new): The method of claim 39 wherein levels of BCSG polynucleotide are determined in bodily fluids.

Claim 70 (new): The method of claim 69 wherein the bodily fluid is whole blood, plasma, serum, a derivative of blood, urine, saliva or other bodily secretion.

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Claim 71 (new): The method of claim 40 wherein levels of BCSG polynucleotide are determined in cells.

Claim 72 (new): The method of claim 40 wherein levels of BCSG polynucleotide are determined in tissues.

Claim 73 (new): The method of claim 40 wherein levels of BCSG polynucleotide are determined in bodily fluids.

Claim 74 (new): The method of claim 73 wherein the bodily fluid is whole blood, plasma, serum, a derivative of blood, urine, saliva or other bodily secretion.

Claim 75 (new): The method of claim 41 wherein levels of BCSG polynucleotide are determined in cells.

Claim 76 (new): The method of claim 41 wherein levels of BCSG polynucleotide are determined in tissues.

Claim 77 (new): The method of claim 41 wherein levels of BCSG polynucleotide are determined in bodily fluids.

Claim 78 (new): The method of claim 77 wherein the bodily fluid is whole blood, plasma, serum, a derivative of blood, urine, saliva or other bodily secretion.

Claim 79 (new): The method of claim 42 wherein levels of BCSG polynucleotide are determined in cells.

Claim 80 (new): The method of claim 42 wherein levels of BCSG polynucleotide are determined in tissues.

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Claim 81 (new): The method of claim 42 wherein levels of BCSG polynucleotide are determined in bodily fluids.

Claim 82 (new): The method of claim 81 wherein the bodily fluid is whole blood, plasma, serum, a derivative of blood, urine, saliva or other bodily secretion.